DEPARTMENT OF HEALTH AND HUMAN SERVICES

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Food and Drug Administration

[Docket Nos. 02M–0298, 02M–0299, 02M–0295, 02M–0381, 02M–0310, 02M–0348, 02M–0335, 02M–0353, 02M–0352, 02M–0336, 02M–0322, 02M–0361, 02M–0412, 02M–0409]

Medical Devices; Availability of Safety and Effectiveness Summaries for Premarket Approval Applications

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is publishing a list of premarket approval applications (PMAs) that have been approved. This list is intended to inform the public of the availability of safety and effectiveness summaries of approved PMAs through the Internet and the agency's Dockets Management Branch.

ADDRESSES: Submit written requests for copies of summaries of safety and effectiveness to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Please cite the appropriate docket number as listed in table 1 of this document when submitting a written request. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the summaries of safety and effectiveness.

FOR FURTHER INFORMATION CONTACT: Thinh Nguyen, Center for Devices and Radiological Health (HFZ–402), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301–594–2186.

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of January 30, 1998 (63 FR 4571), FDA published a final rule that revised 21 CFR 814.44(d) and 814.45(d) to discontinue individual publication of PMA approvals and denials in the **Federal Register**, providing instead to post this information on the Internet on FDA's home page at http://www.fda.gov. In addition, the regulations provide that FDA publish a quarterly list of available safety and effectiveness summaries of PMA approvals and denials that were announced during that quarter. FDA believes that this procedure expedites public notification of these actions because announcements can be placed on the Internet more quickly than they can be published in the **Federal Register**, and FDA believes that the Internet is accessible to more people than the **Federal Register**.

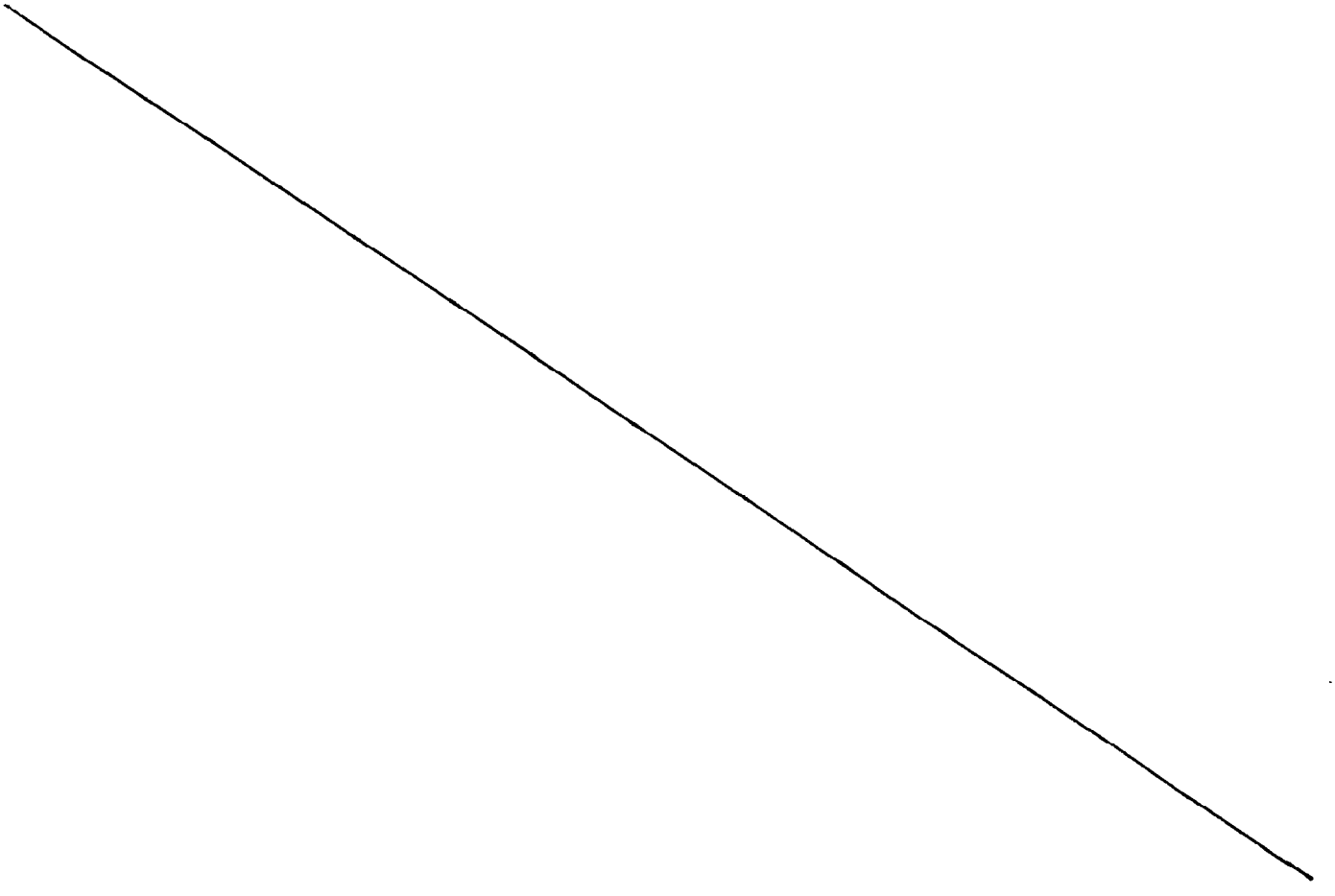
In accordance with section 515(d)(4) and (e)(2) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360e(d)(4) and (e)(2)), notification of an order approving, denying, or withdrawing approval of a PMA will continue to include a notice of opportunity to request review of the order under section 515(g) of the act. The 30-day period for requesting reconsideration of an FDA action under § 10.33(b) (21 CFR 10.33(b)) for notices announcing approval of a PMA begins on the day the notice is placed on the Internet. Section 10.33(b) provides that FDA may, for good cause, extend this 30-day period. Reconsideration of a denial or withdrawal of approval of a PMA may be sought only by the applicant; in these cases, the 30-day period will begin when the applicant is notified by FDA in writing of its decision.

The following is a list of approved PMAs for which summaries of safety and effectiveness were placed on the Internet from July 1, 2002, through September 30, 2002. There were no denial actions during this period. The list

provides the manufacturer's name, the product's generic name or the trade name, and the approval date.

TABLE 1.—LIST OF SAFETY AND EFFECTIVENESS SUMMARIES FOR APPROVED PMAS MADE AVAILABLE JULY 1, 2002, THROUGH SEPTEMBER 30, 2002.

PMA Number/Docket No.	Applicant	Trade Name	Approval Date
P990017(S30)/02M–0298	Guidant Cardiac and Vascular Surgery Group.	ANCURE Aortoiliac Endograft System	April 24, 2002.
P990027(S2)/02M–0299	Bausch & Lomb Surgical, Inc.	TECHNOLAS 217A Excimer Laser System	May 17, 2002.
P870024(S43)/02M–0295	Paragon Vision Sciences	PARAGON CRT (Paflufocon B), PARAGON CRT 100 (Paflufocon D), PARAGON QUADRA RG (Paflufocon B), and PARAGON QUADRA RG 100 (Paflufocon D).	June 13, 2002.
P010031/02M–0381	Medtronic, Inc.	INSYNC ICD Model 7272 Dual Chamber Implantable Cardioverter With Resynchronization Therapy and Model 9969 Application Software.	June 26, 2002.
P000058/02M–0310	Medtronic Sofamor Danek, Inc.	INFUSE BONE GRAFT/LT-CAGE Lumbar Tapered Fusion Device.	July 2, 2002.
P890017(S10)/02M–0348	Cordis Corp.	PALMAZ Balloon-Expandable Stent (Models P104R, P154R, P204R).	July 10, 2002.
P990018(S2)/02M–0335	Menicon Co., Ltd.	MENICON Z (Tisilfocon A) Rigid Gas Permeable Contact Lens	July 12, 2002.
P960040(S26)/02M–0353	Guidant Corp.	VENTAK PRIZM 2 VR/DR Models 1860/1861; VENTAK PRIZM VR/DR Models 1850/1851/1855/1856; VENTAK PRIZM VR/DR HE Models 1852/1853, VENTAK Mini IV Models 1790/1793/1796; and VENTAK Mini III HE Model 1789.	July 18, 2002.
P910077(S37)/02M–0352	Guidant Corp.	VENTAK PRIZM 2 VR/DR Models 1860/1861; VENTAK PRIZM VR/DR Models 1850/1851/1855/1856; VENTAK PRIZM VR/DR HE Models 1852/1853, VENTAK Mini IV Models 1790/1793/1796; and VENTAK Mini III HE Model 1789.	July 18, 2002.
P010039/02M–0336	Siemens Medical Solutions USA, Inc.	Siemens SONOCUR Basic	July 19, 2002.
P020003/02M–0322	Mentor Corp.	Mentor Saline-Filled Testicular Prosthesis	July 19, 2002.
H010004/02M–0361	Guidant Corp.	NEUROLINK System, Including NEUROLINK Stent and Delivery Catheter and NEUROLINK Balloon Dilatation Catheter.	August 9, 2002.
P990026(S8)/02M–0412	Cygnus, Inc.	GlucoWatch G2 Biographer	August 26, 2002.
H020002/02M–0409	SMART Therapeutics, Inc.	Neuroform Microdelivery Stent System	September 11, 2002.



II. Electronic Access

Persons with access to the Internet may obtain the documents at http://www.fda.gov/cdrh/pmapage.html.

Dated: 12/24/02

December 24, 2002.

Linda S. Kahan,
Deputy Director,
Center for Devices and Radiological Health.

[FR Doc. ~~02~~ 03-????? Filed ??-??-~~02~~ 03; 8:45 am]

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